



PATENT
Docket No. 110.02150101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): BISCHOF et al.) Group Art Unit: 3739
Serial No.: 10/810,956) Examiner: Unknown
Confirmation No.: 9825)
Filed: March 26, 2004)
For: THERMAL SURGICAL PROCEDURES AND COMPOSITIONS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Mail Stop Amendment
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Also enclosed is a copy of an International Search Report from a foreign counterpart application. Per M.P.E.P. §609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 forms is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 forms, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Applicants also wish to bring the Examiner's attention to the pending U.S. Application cited in the 1449 forms submitted herewith, as well as any documents, Office Actions that may include rejections of similar claims, and any provisional U.S. patent applications referenced in the pending U.S. application or in its file wrappers. A copy of U.S. Patent Application 10/461,763, which is not available on the U.S.P.T.O. Image File Wrapper (IFW) System, is provided herewith.

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It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if they can be of any assistance during prosecution of the present application.

Respectfully submitted for

BISCHOF et al.

By

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CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in a package addressed to: Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 24th day of February, 2005.


By: Kevin W. Raasch

24 FEB. 2005

Date

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U.S. PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		4,140,109	02/20/79	Savic et al.			
		4,252,130	02/24/81	Le Pivert			
		4,275,734	06/30/81	Mitchiner			
		4,306,568	12/22/81	Torre			
		4,483,341	11/20/84	Witteles			
		5,385,148	01/31/95	Lesh et al.			
		5,654,279	08/05/97	Rubinsky et al.			
		5,720,743	02/24/98	Bischof et al.			
		5,741,248	04/21/98	Stern et al.			
		5,807,395	09/15/98	Mulier et al.			
		5,906,636	05/25/99	Casscells, III et al.			
		6,235,018 B1	05/22/01	Le Pivert			
		10/461,763	06/13/03	Bischof et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
		NONE						

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Examiner Initial	Copy Enclosed	Document Description
	X	Ablin, "An Appreciation and Realization of the Concept of Cryoimmunology," <i>Percutaneous Prostate Cryoablation</i> , St. Louis, MO, Quality Medical Publ., Inc.; 1995; title page, page 136.

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	X	Aliev et al., "Morphological features of regeneration of rabbit aortic endothelium after cryoinduced vascular damage," <i>J. Submicrosc. Cytol. Pathol.</i> , 1999; 31(4):495-502.
	X	Arnott, "On the Treatment of Cancer, by the Regulated Application of an Anesthetic Temperature," J. Churchill, London, England, 1851; title page, and 1 pg. (entire document cannot be copied due to condition of original book).
	X	Arturson, "Capillary Permeability in Experimental Rapid Freezing with Rapid and Slow Rewarming," <i>Acta. Chir. Scand.</i> , 1966; 131:402-407.
	X	Asahina et al., "A Stable State of Frozen Protoplasm with Invisible Intracellular Ice Crystals Obtained by Rapid Cooling," <i>Exp. Cell Res.</i> , 1970; 59:349-358.
	X	Barker et al., "The Effect of Superoxide Dismutase on the Skin Microcirculation after Ischemia and Reperfusion," <i>Prog. Appl. Microcirc.</i> , 1987; 12:276-281.
	X	Bellman et al., "Vascular Reactions after Experimental Cold Injury," <i>Angiology</i> , 1956; 7:339-367.
	X	Bellman et al., "Transformation of the Vascular System in Cold-Injured Tissue of the Rabbit's Ear," <i>Angiology</i> , 1960; 11:108-125.
	X	Bischof et al., "An Analytical Study of Cryosurgery in the Lung," <i>ASME J. Biomech. Eng.</i> , 1992; 114:467-472.
	X	Bischof et al., "Microscale Heat and Mass Transfer of Vascular and Intracellular Freezing in the Liver," <i>J. Heat Trans.</i> , 1993; 115:1029-1035.
	X	Bischof et al., "A Morphological Study of Cooling Rate Response in Normal and Neoplastic Human Liver Tissue: Cryosurgical Implications," <i>Cryobiology</i> , 1993; 30:482-492.
	X	Bischof et al., "Rectal Protection During Prostate Cryosurgery: Design and Characterization of an Insulating Probe," <i>Cryobiology</i> , 1997; 34(1):80-92.
	X	Bischof et al., "Cryosurgery of Dunning AT-1 Rat Prostate Tumor: Thermal, Biophysical, and Viability Response at the Cellular and Tissue Level," <i>Cryobiology</i> , 1997; 34(1):42-69.
	X	Bischof et al., "A parametric study of freezing injury in ELT-3 uterine leiomyoma tumour cells," <i>Human Reproduction</i> , 2001; 16:340-348.

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	X	Bischof, "Mechanisms of Injury During Freezing: Cryosurgery of Prostate," Presentation, Minnesota's Medical Device Community Forum, April 24-25, 2003, Minneapolis, MN, 20 pgs.
	X	Bischof, John C., "Establishing the Efficacy of Cryomyolysis - Cryosurgery of Uterine Fibroids," Grant Abstract, Grant No. NSF-BES 9703326 [online]. National Science Foundation - BES Division, 1997-09-15 to 2002-08-31 [retrieved on 2003-07-01]. Retrieved from the Internet: <URL: https://www.fastlane.nsf.gov/servlet/showaward?award=9703326 >; 2 pgs.
	X	Bischof, John C., "Establishment of Mechanisms of Cryodestruction," Grant Abstract, Grant No. 5R29CA075284-05 [online]. National Cancer Institute, 1998-07-15 to 2003-06-30 [retrieved on 2003-07-01]. Retrieved from the Internet:<URL: ">http://crisp.cit.nih.gov/crisp/CRISP_LIB.getdoc?textkey=6513112&p_grant_num=5R29CA075284-05&p_query=&ticket=3953348&p_audit_session_id=18077139&p_keywords=> ; 2 pgs.
	X	Bonney et al., "Cryosurgery in Prostatic Cancer: Elimination of Local Lesion," <i>Urology</i> , 1983; 22:8-15.
	X	Bourne et al., "Analysis of Microvascular Changes in Frostbite Injury," <i>J. Surg. Res.</i> , 1986; 40:26-35.
	X	Bowers et al., "Ultrastructural Studies of Muscle Cells and Vascular Endothelium Immediately after Freeze-Thaw Injury," <i>Cryobiology</i> , 1973; 10:9-21.
	X	Chao et al., "Pre-treatment inflammation induced by TNF-alpha cryosurgical injury on human prostate cancer," <i>Cryobiology</i> , 2004;49(1):10-27.
	X	Chosy et al., "Monitoring Renal Cryosurgery: Predictors of Tissue Necrosis in Swine," <i>Journal of Urology</i> , 1998; 159:1370-1374.
	X	Clarke et al., "Timing Dependency in Cryo-Chemo Combination Therapy: Model Cell Systems," <i>Cryobiology</i> , Abstracts, 36 th Annual Meeting, 1999; 39:320.
	X	Comini et al., "Thermal Aspects of Cryosurgery," <i>ASME J. Heat Transfer</i> , 1976; 98:543-549.
	X	Cooper, "Cryogenic Surgery. A New Method of Destruction or Extirpation of Benign or Malignant Tissues," <i>New Eng. J. Med.</i> , 1963; 268:743-749.

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	X	Cooper et al., "Analytical Prediction of the Temperature Field Emanating from a Cryogenic Surgical Cannula," <i>Cryobiology</i> , 1970; 7:79-93.
	X	Cooper et al., "Rate of Lesion Growth Around Spherical and Cylindrical Cryoprobes," <i>Cryobiology</i> , 1971; 7:183-190.
	X	Cosman et al., "An Integrated Cryomicroscopy System," <i>Cryo-Letters</i> , 1989; 10:17-38.
	X	Crisman et al., "Studies on Gangrene Following Cold Injury. V: The Use of Fluorescein as an Indicator of Local Blood Flow: Fluorescein Tests in Experimental Frostbite," <i>J. Clin. Invest.</i> , 1947; 26:268-276.
	X	Cummings et al., "Increased vascular permeability evoked by cold injury," <i>Pathology</i> , 1973; 5:107-116.
	X	Dachs et al., "The molecular response of mammalian cells to hypoxia and the potential for exploitation in cancer therapy," <i>Brit. J. Cancer</i> , 1996; 74(Suppl. 27):S126-S131.
	X	Daum et al., "Vascular Casts Demonstrate Microcirculatory Insufficiency in Acute Frostbite," <i>Cryobiology</i> , 1987; 24:65-73.
	X	Diller et al., "Water Transport Through a Multicellular Tissue During Freezing: A Network Thermodynamic Modeling Analysis," <i>Cryo-Letters</i> , 1990; 11:151-162.
	X	Dilley et al., "Laboratory and Animal Model Evaluation of the Cryotech LCS 2000 in Hepatic Cryotherapy," <i>Cryobiology</i> , 1993; 30:74-85.
	X	Echlin, <i>Low-Temperature Microscopy and Analysis</i> , New York, NY, Plenum Press, 1992, cover page, title page and table of contents only:11 pgs.
	X	Elliot et al., "Ice Pattern Formation in Mammary Tissue from Sprague-Dawley Rats," <i>Cryobiology</i> , Abstracts, 35 th Annual Meeting, 1998; 37:451.
	X	Folkman, "The Vascularization of Tumors," <i>Sci. Am.</i> , 1976; 234:59-64 & 70-73.
	X	Fraser et al., "Observations on Ultra-Frozen Tissue," <i>Br. J. Surg.</i> , 1967; 54:770-776.

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	X	Fukumura et al., "Tumor Necrosis Factor Alpha-induced Leukocyte Adhesion in Normal and Tumor Vessels: Effect of Tumor Type, Transplantation Site, and Host Strain," <i>Cancer Research</i> , 1995; 55(21):4824-4829.
	X	Gage et al., "Effect of Varying Freezing and Thawing Rates in Experimental Cryosurgery," <i>Cryobiology</i> , 1985; 22(2):175-182.
	X	Gage, "Cryosurgery in the Treatment of Cancer," <i>Surg., Gynecol. Obstet.</i> , 1992; 174(1):73-92.
	X	Gage et al., "Mechanisms of Tissue Injury in Cryosurgery," <i>Cryobiology</i> , 1998; 37(3):171-186.
		Gilbert et al., "Real Time Ultrasonic Monitoring of Hepatic Cryosurgery," <i>Cryobiology</i> , 1985; 22:319-330.
	X	Gilbert et al., "Solid-Liquid Interface Monitoring with Ultrasound During Cryosurgery," <i>ASME 85-WA/HT-83</i> , 1985:1-10.
	X	Gill et al., "Renal cryosurgery," <i>Urology</i> , 1999, 54:215-219.
	X	Gupta et al., "A Novel Technique for Culture of Human Dermal Microvascular Endothelial Cells Under Either Serum-free or Serum-supplemented Conditions: Isolation by Panning and Stimulation with Vascular Endothelial Growth Factor," <i>Exp. Cell Res.</i> , 1997; 230(2):244-251.
	X	Han et al., "Modification and Use of Eutectic Formation to Enhance Direct Cell Injury," Powerpoint Presentation, <i>39th Annual Meeting of the Society for Cryobiology</i> , Breckenridge, CO, July 28-31, 2002; 18 pgs.
	X	Han et al., "Modification and use of eutectic formation to enhance direct cell injury," Abstract, <i>39th Annual Meeting of the Society for Cryobiology</i> , Breckenridge, CO, July 28-31, 2002; <i>Cryobiology</i> , 2002; 45:2 pgs.
	X	Han et al., "Thermal property measurements in biological solutions at subzero temperatures," Abstract, <i>39th Annual Meeting of the Society for Cryobiology</i> , Breckenridge, CO, July 28-31, 2002; <i>Cryobiology</i> , 2002; 45: 3 pgs.
	X	Han et al., "Phase Change Behavior of Biomedically Relevant Solutions," <i>Proceedings of IMECE2002, ASME International Mechanical Engineering Congress & Exposition</i> , IMECE2002-32549, New Orleans, LA, Nov. 17-22, 2002; 7 pgs.

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	X	Han et al., "Enhancement of cell and tissue destruction in cryosurgery by use of eutectic freezing," <i>Powerpoint Presentation, 2003 SPIE Conference</i> , San Jose, CA, Jan. 25-31, 2003; 25 pgs.
	X	Han et al., "Enhancement of Direct Cell Injury During Freezing AT-1 Tumor Tissues by Use of Eutectic Crystallization," <i>2003 Summer Bioengineering Conference</i> , Key Biscayne, FL, June 25-29, 2003; 2 pgs.
	X	Hayakawa et al., "Comparative Immunological Studies in Rats Following Cryosurgery and Surgical Excision of 3-Methylcholanthrene-Induced Primary Autochthonous Tumors," <i>Gann</i> , 1982; 73:462-469.
	X	Hayes et al., "Prediction of Local Cooling Rates and Cell Survival During the Freezing of a Cylindrical Specimen," <i>Cryobiology</i> , 1988; 25:67-82.
	X	Hoffmann et al., "Cryosurgery of Normal and Tumor Tissue in the Dorsal Skin Flap Chamber: Part I-Thermal Response," <i>ASME J. Biomech. Eng.</i> , 2001; 123:301-309.
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	X	Hoffman et al., "Investigation of the Mechanism and the Effect of Cryoimmunology in the Copenhagen Rat," <i>Cryobiology</i> , 2001; 41:59-68.
	X	Hoffmann et al., "The Cryobiology of Cryosurgical Injury," <i>Urology</i> , 2002; 60(2 Suppl 1):40-49.
	X	Hynsjo et al., "Use of Factorial Experimental Design to Delineate the Strong Calcium- and pH-Dependent Changes in Binding of Human Surfactant Protein-A to Neutral Glycosphingolipids-A Model for Studies of Protein-Carbohydrate Interactions," <i>Anal. Biochem.</i> , 1995; 225(2):305-314.
	X	Inserte et al., "The Role of Na ⁺ -H ⁺ Exchange Occuring During Hypoxia in the Genesis of Reoxygenation-induced Myocardial Oedema," <i>J. Mol. Cell. Cardiol.</i> , 1997; 29(4):1167-1175.
	X	Isaacs et al., "Establishment and Characterization of Seven Dunning Rat Prostatic Cancer Cell Lines and Their Use in Developing Methods for Predicting Metastatic Abilities of Prostatic Cancers," <i>Prostate</i> , 1986; 9:261-281.

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	X	Iyengar et al., "The effects of an iron chelator on cellular injury induced by vascular stasis caused by hypothermia," <i>J. Vascular Surg.</i> , 1990; 12:545-551.
	X	Jackson et al., "Vascular Endothelial Growth Factor (VEGF) Expression in Prostate Cancer and Benign Prostatic Hyperplasia," <i>J. Urol.</i> , 1997; 157:2323-2328.
	X	Jacob et al., "An Assessment of Tumor Cell Viability after <i>in Vitro</i> Freezing," <i>Cryobiology</i> , 1985; 22:417-426.
	X	Jain, "Analysis of Heat Transfer and Temperature Distributions in Tissues During Local and Whole-Body Hyperthermia," <i>Heat Transfer in Medicine and Biology, Volume 2</i> , New York, NY, Plenum Press, 1985, Chapter 16, pgs. 3-54.
	X	Jain, "Transport of Molecules in the Tumor Interstitium: A Review," <i>Cancer Res.</i> , 1987; 47:3039-3051.
	X	Kane, "Ultrasound-Guided Hepatic Cryosurgery for Tumor Ablation," <i>Seminars in Interventional Radiology</i> , 1993; 10:132-142.
	X	Keanini et al., "Optimization of Multiprobe Cryosurgery," <i>ASME J. Heat Transfer</i> , 1992; 114:796-801.
	X	Kourosh et al., "Microscopic study of coupled heat and mass transport during unidirectional solidification of binary solutions—I. Thermal analysis," <i>Int. J. Heat Mass Transfer</i> , 1990; 33(1):29-38.
	X	Kruuv, "Effects of Pre- and Post-thaw Cell-to-Cell Contact and Trypsin on Survival of Freeze-Thaw Damaged Mammalian Cells," <i>Cryobiology</i> , 1986; 23:126-133.
	X	Larese et al., "Antifreeze Proteins Induce Intracellular Nucleation," <i>Cryo-Letters</i> , 1996; 17:175-182.
	X	Lewis et al., "Vascular Reactions of the Skin to Injury. Part III.—Some Effects of Freezing, of Cooling, and of Warming," <i>Heart</i> , 1926; 13:27-60.
	X	Lim et al., "Growth of an Androgen-Sensitive Human Prostate Cancer Cell Line, LNCaP, in Nude Mice," <i>Prostate</i> , 1993; 22(2):109-118.
	X	Love, "The Freezing of Animal Tissue," <i>Cryobiology</i> , New York, NY, Academic Press, 1966, Chap. 7, pgs. 317-405.

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	X	Lubaroff et al., "Experience with an Animal Model for the Study of Prostatic Carcinoma," <i>Trans. Am. Assoc. Genito-Urin. Surgeons</i> , 1978; 69:72-77.
	X	Lubaroff et al., "Immunologic Studies of Prostatic Cancer Using the R3327 Rat Model," <i>Trans. Am. Assoc. Genito-Urin. Surgeons</i> , 1979; 70:60-63.
	X	Ludwin, "Survival of Tumor Material after Freezing at -79°C," <i>Biodynamica</i> , 1951; 7(131):53-55.
	X	Manson et al., "Evidence for an Early Free Radical-Mediated Reperfusion Injury in Frostbite," <i>Free Radical Biology & Medicine</i> , 1991; 10:7-11.
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	X	Mazur, "The Role of Cell Membranes in the Freezing of Yeast and Other Single Cells," <i>Ann. N.Y. Acad. Sci.</i> , 1965; 125:658-676.
	X	Mazur, "Cryobiology: The Freezing of Biological Systems," <i>Science</i> , 1970; 168:939-949.
	X	Mazur et al., "Relative Contributions of the Fraction of Unfrozen Water and of Salt Concentration to the Survival of Slowly Frozen Human Erythrocytes," <i>Biophys. J.</i> , 1981; 36:653-675.
	X	Mazur, "Freezing of living cells: mechanisms and implications," <i>Am. J. Physiol.</i> , 1984; 247:C125-C142.
	X	McGann et al., "Factors affecting the repair of sublethal freeze-thaw damage in mammalian cells. II. The effects of ouabain," <i>Cryobiology</i> , 1974; 11:332-339.
	X	McGann et al., "Factors affecting the repair of sublethal freeze-thaw damage in mammalian cells. I. Suboptimal temperature and hypoxia," <i>Cryobiology</i> , 1975; 12:530-539.

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	X	McGrath et al., "An Experimental Comparison of Intracellular Ice Formation and Freeze-Thaw Survival of Hela S-3 Cells," <i>Cryobiology</i> , 1975; 12:540-550.
	X	McGrath, "Membrane Transport Properties," <i>Low Temperature Biotechnology—Emerging Applications and Engineering Contributions</i> , ASME BED, 1988; 10:273-331.
	X	McHugh et al., "Complications and Postoperative Management," <i>Percutaneous Prostate Cryoablation</i> , St. Louis, MO, Quality Medical Publishing, Inc., 1995; title page, pgs. 129-135.
	X	Mundth et al., "Treatment of Experimental Frostbite with Low Molecular Weight Dextran," <i>Journal of Trauma</i> , 1964; 4:246-257.
	X	Mundth, "Studies on the Pathogenesis of Cold Injury. Microcirculatory Changes in Tissue Injured by Freezing," <i>Proc. Symp. Arctic Biol. Med. IV. Frostbite</i> , Feb. 17-19, 1964; 51-72.
	X	Nagle et al., "Cultured Chinese Hamster Cells Undergo Apoptosis after Exposure to Cold but Nonfreezing Temperatures," <i>Cryobiology</i> , 1990; 27:439-451.
	X	Neel et al., "Ischemia Potentiating Cryosurgery of Primate Liver," <i>Ann. Surg.</i> , 1971; 174:309-318.
	X	Neel et al., "Cryonecrosis of Normal and Tumor-Bearing Rat Liver Potentiated by Inflow Occlusion," <i>Cancer</i> , 1971; 28:1211-1218.
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